

3.0 510(k) SummaryPage 1 of 1

Sponsor: Synthes (USA)
Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941

Device Name: Synthes (USA) 1.5mm Headless Compression Screws

Classification: Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener.

Predicate Device: Synthes 3.0mm Headless Compression Screws
Synthes Stainless Steel Modular Hand System

Device Description: The Synthes 1.5mm Headless Compression Screws are solid bone fixation screws featuring a partially threaded shaft and threaded head. The screws are available in stainless steel and titanium.

Intended Use: Synthes 1.5mm Headless Compression Screws are indicated for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodeses of small joints.

**Substantial
Equivalence:** Information presented supports substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Mr. Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380

JUL 31 2009

Re: K090949

Trade/Device Name: Synthes (USA) 1.5mm Headless Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 10, 2009
Received: July 15, 2009

Dear Mr. Nittinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

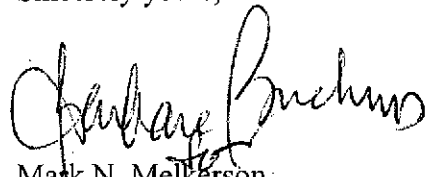
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/cdrh/comp/> for the Center for Devices and Radiological Health's

Page 2 – Mr. Karl J. Nittinger

(CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkersen", is written over the typed name.

Mark N. Melkersen
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0

Indications for Use

510(k) Number (if known): K090949

Device Name: Synthes (USA) 1.5mm Headless Compression Screws

Indications for Use:

Synthes 1.5mm Headless Compression Screws are indicated for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodeses of small joints.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonathan J. for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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